

### **Remarks**

The Examiner has required a restriction between the claims of Group I (1-10 and 17), Group II (claims 11-15) and Group III (claims 16, 19-20). In addition, the Examiner has required an election of species. These requirements are respectfully traversed. Reconsideration and withdrawal thereof are requested.

### **1. RESPONSE TO RESTRICTION REQUIREMENT**

The Examiner has urged that the claims that Groups I –III do not relate to a single general inventive concept under PCT Rule 13.1. Applicants submit that the Examiner's position is improper for two reasons.

First of all, the Examiner will note that, during the international phase, unity of invention between all of the claims was found, except with respect to use claim 17. Applicants submit that the Examiner's present attempt to further divide Applicant's claims shows that the Examiner has not properly analyzed unity of invention under PCT Rule 13. An international application, such as the present application, which complies to the unity of invention requirements under PCT Rule 13 must be accepted by all of the designated and elected offices, including the USPTO, since Article 27 (1) of the treaty does not permit any national law or national office to require compliance with different regulations relating to the contents of the international application. Thus, the U.S. application must be examined for unity of invention consistent with the Patent Cooperation Treaty. The U.S. Examiner is not permitted to simply give verbal assent to PCT Rule 13, while failing to properly analyze unity of invention under the rule. See *Caterpillar Tractor Co. v Commission of Patent and Trademarks*, 231 USPQ 590 (E.D.VA 1986).

Secondly, under PCT Rule 13, the application fulfills the unity of invention requirement when there is a "technical relationship among those inventions involving one or more of the same or corresponding technical features." In the present case, the Examiner has

alleged that there is no common technical feature, because the Examiner alleges that the shared technical feature is rendered obvious by the publication to MELNYK et al. Applicants submit that the Examiner has wrongly interpreted MELNYK, and has failed to recognize the non-obvious special technical feature which is common to the present claims.

The MELNYK publication discloses a ligation, in solution and by a hydrazone link, between two peptides, one peptide bearing a lipophilic chain and an aldehyde function and the other one being modified at the lysine side chain by a hydrazine group. A hydrazone link is then produced in solution. This synthesis however, has some drawbacks mentioned in the present Specification (page 1, line 36 to page 2, line 11) as well as limitations indicated in the W. Zeng document (page 2, line 12-18 of the Specification) concerning the lipophilic part of the peptide.

The aim of the present invention is to avoid the aforementioned drawbacks, and namely to improve yields of the lipopeptides obtained by chemical ligation, not requiring the use of thiol chemistry and allowing a direct coupling of a lipophilic compound to a completely deprotected peptide (Specification page 2, lines 32-36). For this purpose, there is a need for a new lipopeptide synthesis strategy that should meet the criteria as mentioned in the present application (Specification page 3, lines 4-20).

These objectives are obtained in the present invention by creating a hydrazide link between a peptide and a compound that is linked thereto, said link being stable and not a disulphide link presenting the drawbacks of the prior art.

Accordingly, this is the technical problem solved by the invention defined in claim 1.

The claimed process exhibits effects that are not taught by MELNYK. For Example:

1. The hydrazide link produced between the peptide and the compound A is very stable, especially over a wide range of pH values and in vivo (page 4, lines 1-3);
2. The coupling reaction between compound A and preferably completely deprotected peptide makes it possible to avoid any step of deprotecting side chains of the peptide with a strong acid following the coupling reaction (page 4, line 34 to page 5, line 4);
3. The coupling reaction takes place under very mild operating conditions (page 5, lines 15-19).

In summary, the MELNYK document does not render obvious the claimed synthesis in liquid phase of a lipopeptide by acetylating a lipid bearing alcohol or carboxylic function previously activated by succinimide derivatives and a peptide bearing hydrazine group for generating a hydrazide link. Moreover, this acetylation reaction is carried out in specific conditions, at acid pH, allowing then the coupling between a peptide and a lipid, said lipid having unsaturated functions.

For the above reasons, Applicants submit that the Examiner's restriction requirement is improper, so that all the claims should be examined together in this application. Applicants submit that, properly analyzed under PCT Rule 13, there is indeed unity of invention in the present application.

However, in order to be fully responsive to the Restriction Requirement, Applicants provisionally elect, with traverse, to prosecute the claims of group I, that is claims 1-10 and 17.

## **2. RESPONSE TO ELECTION OF SPECIES**

The Examiner has also requested an Election of Species relative to compound A. In response, Applicant's elect the species identified as "lipids" in claim 8. Applicants submit that all of the claims are readable on this elected species.

However, although Applicants have elected a species from which to initiate prosecution, this election should not be the basis for the Examiner to limit the application to only the elected species. As set forth in MPEP § 803.02, once the Examiner has determined that the elected species is allowable, examination of the markush-type claim must be extended to other species encompassed by the claim.

Applicant reminds the Examiner of this requirement because the Examiner's comments on page 3 of the Office Action seems to suggest an attempt by the Examiner to limit Applicant's claims because the species allegedly do not relate to a single general inventive concept. But in making these comments, the Examiner is improperly mixing the principles of a Restriction Requirement under 35 USC § 121 and the procedural mechanism of an election of species. While the Examiner may properly request the Applicant to elect a species from which to initiate prosecution, the Examiner may not refuse to ultimately examine the merits of Applicant's broad generic claim. This is true even if the broad generic claim covers a plurality of independent patentable species. As stated by Judge Rich of the CCPA:

"It is elementary patent law that the number of "species" "covered" by a patent having a generic claim is virtually without limit notwithstanding the limitation of Rule 141-5 species "specifically claimed." So the discretionary power to limit one application to one invention is no excuse at all for refusing to examine a broad generic claim- no matter how broad, which means no matter how many independently patentable inventions may fall within." In re *Weber*, 198 USPQ 328, 331-332 (CCPA 1978).

In summary, Applicant's respectfully traverse the Examiner's restriction and election of species requirements, but provisionally elect to prosecute the claims of Group I (1-10 and 17)

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and provisionally elect for purposes of initiating prosecution the species of compound A represented by "lipids." Favorable action and early allowance of all the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By  # 58,475  
for Leonard R. Svensson  
Registration No.: 30,330  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
12770 High Bluff Drive  
Suite 260  
San Diego, California 92130  
(858) 792-8855  
Attorney for Applicant